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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,749	05/02/2007	Marcel Boosten	2004P00300WOUS	5778

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BRIARCLIFF MANOR, NY 10510

EXAMINER

PENG, BO JOSEPH

ART UNIT	PAPER NUMBER
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3768

NOTIFICATION DATE	DELIVERY MODE
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04/09/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/597,749	BOOSTEN, MARCEL	
	Examiner	Art Unit	
	BO J. PENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is responsive to the Amendments/Arguments filed on 03/05/2012. Claims 18 and 27 have been amended. Claims 1-17 has been cancelled. Claims 18-35 are now pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 18-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strommer et al. (Pub. No. 2005/0033149, hereinafter Strommer '149) in view of Verard et al. (US 2004/0097805, hereinafter Verard '805), Hofland et al. (Pat. No. 5,800,354,

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hereinafter Hofland '354), and Kundu et al. (Knowledge-based ECG interpretation: a critical review, 2000, Pattern Recognition, 33, 351-373, hereinafter Kundu '2000).

In re claims 18 and 27, Strommer '149 discloses a system and method for controlling an interventional procedure in an organ of a patient (see abstract) that comprises: (i) an intervention device comprising detectable markers positioned within a volume of the target organ, (ii) a displaceable catheter for performing an intervention of the interventional procedure, and (iii) a stereotactic navigation system to position the detectable markers and displaceable catheter within the target organ (see para 83); an imaging unit arranged to acquire images of the target organ along with the detectable markers and the displaceable catheter (see paras 96-102); a computing unit configured to carry out the steps (i) interrelating the spatial positions of the detectable markers (see paras 96-102), monitoring the spatial position of the displaceable catheter; determining a discrepancy between the spatial position of the displaceable catheter and the spatial roadmap and calculating a navigational correction (see paras 43 and 96-102); and controlling the navigation system to apply the navigational correction to the position of the displaceable catheter (see paras 96-102); and a user interface arranged to display images of (i) the target organ, (ii) the spatial position of the detectable markers, (iii) the displaceable catheter, and (iv) the spatial roadmap (see paras 96-102); and a control screen displaying the correction to be applied to the navigation system and accepting interactive user input for the correction (see paras 96-102).

Strommer '149 fails to teach a plurality of detectable markers provided on a distal portion per catheter, the plurality of detectable markers of the respective distal portions

being positioned in a substantially evenly distributed manner within a volume of the target organ to enable a visualization of a corresponding catheter.

Verard '805 teaches a plurality of detectable markers provided on a distal portion per catheter, the plurality of detectable markers of the respective distal portions being positioned in a substantially evenly distributed manner within the a volume of target organ to enable a visualization of a corresponding catheter within the target organ (figs. 4b, 7-11, 15A, 22-23); constructing an internal motion-corrected target organ-oriented three-dimensional coordinate system based on the images being used as the features on which to base motion correction; generating a spatial roadmap representing an envisaged trajectory of the displaceable catheter within the motion-corrected target organ-oriented three-dimensional coordinate system by interrelating the spatial positions of the detectable markers within the motion-corrected target organ-oriented three-dimensional coordinate system (figs 6-11, 13, para 62-67, 73-74, 87-88, 99, etc).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the method/device of Strommer '149 to include the multiple of detectable markers of Verard '805 in order to increase the number of markers for better motion and position detection. It also would be obvious to be able to display the spatial position of these further detectable marker of the displaceable catheter after detection.

The combine device of Strommer '149 and Verard '805 fails to teach using supplementary information, wherein the supplementary information for generating the spatial roadmap includes measured temporal electrical activity of the organ and related

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time moments of the measured temporal electrical activity of different points of a measurement of temporal electrical activity, wherein a pattern of contraction of the organ is derived and irregularities in a conductivity of electrical signals are identified, further wherein the derived pattern of organ contraction and the identified irregularities are used as the supplementary information for generating the spatial roadmap.

Hofland '354 teaches using supplementary information, wherein the supplementary information for generating the spatial roadmap includes measured temporal activity of the organ and related time moments of the measured temporal activity of different points of a measurement of temporal activity, wherein a pattern of contraction of the organ is derived and irregularities are identified, further wherein the derived pattern of organ contraction and the identified irregularities are used as the supplementary information for generating the spatial roadmap (col. 9, lines 8-22, fig. 7).

Hofland '354 fails to explicitly teach measure temporal electrical activity of the organ and irregularities/abnormality in a conductivity of electrical signals from ECG signal even though it would be inherent that ECG measures temporal electrical activity of the heart and irregularities/abnormality in a conductivity of electrical signals.

Kundu '2000 further exemplifies an ECG system that measures temporal electrical activity of the heart and irregularities/abnormality in a conductivity of electrical signals (whole documents, figs. 1 & 2 & 7, page 360, section Diagnosis of ECG patterns).

It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to conclude that the combine knowledge of Hofland '354 and Kundu

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'2000 teaches using supplementary information, wherein the supplementary information for generating the spatial roadmap includes measured temporal electrical activity of the organ and related time moments of the measured temporal electrical activity of different points of a measurement of temporal electrical activity, wherein a pattern of contraction of the organ is derived and irregularities in a conductivity of electrical signals are identified, further wherein the derived pattern of organ contraction and the identified irregularities are used as the supplementary information for generating the spatial roadmap.

Therefore, it would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the method/device of Strommer '149 to include the multiple of detectable markers of Verard '805 in order to increase the number of markers for better motion and position detection and to include the supplementary ECG information obtained from the combined device of Hofland '354 and Kundu '2000 to ensure more precise motion correction with respect to different organ physiological conditions.

In re claims 19-26 and 28-35, Strommer discloses the computing unit configured to carry out the steps: monitoring the spatial position of the detectable markers; determining a displacement of a detectable marker; recalculating the roadmap based on the displacement; and sending a signal to the navigation system to automatically position the displaceable catheter (see paras 96-102), further comprising an imaging unit arranged to acquire high resolution images (see para 71), further comprising the imaging unit employing an X-ray beam or magnetic resonance acquisition (see para

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71), further comprising an imaging unit arranged to acquire images by rotational scan of an X-ray source around the target organ (see para 71), the intervention device further comprising a catheter adapted to measure cardiac action potentials within the target organ (see paras 84-87), wherein the roadmap is arranged to represent a burning path for an ablating catheter (see para 56), sending a signal to warn the operator of a change in configuration of the detectable markers (see paras 96-102), further comprising the user interface arranged to display actual electrical activity of tissue of the target organ (see paras 84-87).

Response to Arguments

Applicant's arguments with respect to claims 18-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BO J. PENG whose telephone number is (571)270-1792. The examiner can normally be reached on Monday thru Thursday: 8:30am-5:00pm, Alternate Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BO J. PENG /
Examiner, Art Unit 3768

/LONG V. LE/
Supervisory Patent Examiner, Art Unit 3768